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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,444	07/11/2005	Gregor Reid	15339	7350
23389 7590 01/13/2010 SCULLY SCOTT MURPHY & PRESSER, PC 400 GARDEN CITY PLAZA SUITE 300 GARDEN CITY, NY 11530				
EXAMINER LEAVITT, MARIA GOMEZ				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/509,444

Applicant(s)

REID ET AL.

Examiner

MARIA LEAVITT

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10-02-2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 5, 7, 9, 11, 13, 17, 18 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 7, 9, 11, 13, 17, 18 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Detailed Action

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Applicant's amendment filed on 10-02-2009 has been entered.
3. Status of claims. Claims 1, 2, 5, 7, 9, 11, 13, 17, 18 and 21-26 are currently pending. Claims 4 and 10 have been canceled; claims 1, 2, 5, 7, 9, 11, 13, 17 and 18 have been amended; and claims 21-26 have been added by Applicants' amendment filed on 10-02-2009.
4. Therefore, claims 1, 2, 4, 5, 7, 9, 11, 13, 17, 18 and 21-26 are currently under examination to which the following grounds of rejection are applicable.

Withdrawn objections/rejections in response to Applicants' arguments or amendments

Claims objection

In view of Applicants' amendment of claims 1, 2, 5, 7, 9, 11, 13, 17 and 18, objection to claims 1, 2, 4, 5, 7, 9-11, 13, 17 and 18 has been withdrawn.

Objections maintained in response to Applicants' arguments or amendments

Claim Rejections - 35 USC § 103

Claims 1, 2, 4, 5, 7, 9, 11 and 13 remain rejected and new claims 21, 23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chrisope et al., (US Patent 6,468,526, Date of filing Dec 21, 2001), as evidenced by Macfarlane et al (1999, BMJ pp. 999-

1003), in view of Hans et al., (US Patent 7,220,418; Date of PCT Publication Jan. 11, 2001) and further in view of Falsen et al., (1999, Journal of Systematic Bacteriology, pp. 217-221).

Note that Falsen et al., teaches the discovery of a new species of the genus *Lactobacillus*: *Lactobacillus iners*, Genbank-Y16329 (see STN search result 1 and Genebank sequence search for Y16329).

Response to Applicants' arguments as they relate to rejection of claims 1, 2, 4, 5, 7, 9-11 and 13 under - 35 USC § 103

At pages 7-9 of the remarks filed on 10-02-2009, Applicants essentially argue that: 1) Clindamycin is a protein synthesis inhibitor lincosamide antibiotic and not a probiotic, as stated at page 5 of the office action of 04-08-2009, 2) Chrisope does not teach or suggest treatment of bacterial vaginosis through a treatment with a first probiotic, *Lactobacillus iners*, and a second probiotic as required by the instant invention, 3) Falsen does not teach a method or treatment involving *Lactobacillus* or the specific strain *iners*, (page 217, col. 2, lines 8-12), 4) MacFarlane does not teach specific strains of *Lactobacilli* including *L. iners*, 5) Hans discloses treatment of inflammatory disorders of the gastro-intestinal including the use of *L. iners* but not methods of establishing a healthy bacterial flora through a treatment of a first probiotic, *L. iners* and a second probiotic as required by the claimed invention. The above arguments have been fully considered but deemed unpersuasive.

Regarding 1), the specification as filed does not provide a closed definition of the term "prebiotic" but discloses some of its attributes such as "a prebiotic also includes a nutrient utilized by lactobacilli or bifidobacteria to stimulate and/or enhance growth of lactobacilli or bifidobacteria relative to pathogenic bacteria." (page 5, paragraph 1). To the extent that

treatment of vaginal infections comprises administering to a female clindamycin cream followed by *L. crispatus* CTV-05 capsules as disclosed by Chrisope, wherein said treatment enhances colonization by Lactobacilli as compared to a control group treated solely with clindamycin (col. 31, lines 40-50), clindamycin falls within the scope of a prebiotic. Furthermore, Chrisope describes that *Lactobacillus* is administered with a biologically active binding agent comprising a carbohydrate and a proteinaceous material that maintains genetically active cells for a period of at least 12 months *in vitro* (col. 8, lines 20-29), which also falls within the scope of administration of a probiotic, e.g., Lactobacillus, with a prebiotic, e.g., carbohydrate and a proteinaceous material.

Regarding 2), Chrisope clearly discloses administration of *L. crispatus* CTV-05 capsules twice daily for three days (col. 30, lines 37-40), reading on a treatment with a first probiotic, *Lactobacillus iners*, and a second probiotic, as recited in claim 1.

Regarding 3), in response to Applicants' arguments that, "Falsen does not teach a method or treatment involving *Lactobacillus* or the specific strain *iners*", note that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Regarding 4), MacFarlane is cited to define the term probiotic which was well known in the prior art to define commercial preparations of *lactobacilli*.

Regarding 5), Hans complements the teachings of Chrisope and Falsen by disclosing non-pathogenic *Lactobacillus* species, well known in the art, including *Lactobacillus iners*. The genus of *Lactobacillus* includes various strains including *Lactobacillus jensenii*, *Lactobacillus*

crispatus CTV-05 and *Lactobacillus iners*. Thus, if administration of a therapeutically effective amount to a female a vaginal of non pathogenic, isolated strain of *Lactobacillus crispatus* CTV-05 prevents and treats vaginal infections, administration to a female of a therapeutically effective amount non pathogenic *Lactobacillus iners* should be reasonably expected to treat or prevent vaginal infections for the same reason *Lactobacillus crispatus* CTV-05 treats vaginal infections- both are non pathogenic strains of the genus *Lactobacillus*.

Claims 17 and 18 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Chrisope et al., (US Patent 6,468,526, Date of filing Dec 21, 2001) in view of Hans et al., (US Patent 7,220,418; Date of PCT Publication Jan. 11, 2001) and Falsen et al., Journal of Systematic Bacteriology, 1999, 217-221, of record) as applied to claims 1, 2, 4, 5, 7, 9-11 and 13 above, and further in view of Macfarlane et al (1999, BMJ pp. 999-1003).

Response to Applicants' arguments as they relate to rejection of claims 17 and 18 under - 35 USC § 103

At page 9, Applicants essentially argue that the combination of Chrisope, Hans, Falsen and Macfarlane does not obviate the instant claims in relation to a prebiotic being inulin, fructo-oligosaccharides or milk. Such is not persuasive.

As set forth in the paragraph above, the specification as filed does not provide a closed definition of the term "prebiotic" but discloses some attributes such as "a prebiotic also includes a nutrient utilized by *lactobacilli* or bifidobacteria to stimulate and/or enhance growth of *lactobacilli* or bifidobacteria relative to pathogenic bacteria." (page 5, paragraph 1). To the extent that Chrisope discloses that treatment of vaginal infections comprises administering to a

female of clindamycin cream followed by *L. crispatus* CTV-05 capsules, wherein said treatment enhances colonization by *Lactobacilli* as compared to a control group treated solely with clindamycin (col. 31, lines 40-50), clindamycin falls within the scope of a prebiotic.

Furthermore, Macfarlane is prior art that teaches that it is well established in the art to use inulins and their derivatives, the fruto-oligosaccharides, as effective prebiotics because they selectively stimulate growth and activities of *lactobacilli*, thereby improving health (p. 999, col. 1, paragraph 1). Consequently, it would have been *prima facie* obvious for one of ordinary in the art in an attempt to improve the method for establishing a healthy bacterial flora to have replaced a clindamycin cream used in combination with *Lactobacilli* as taught by Chrisope with any of the known prebiotics including inulins and fruto-oligosaccharides to stimulated growth and activities of *lactobacilli* in order to treat and prevent vaginal infections with a reasonable expectation of success.

New grounds of rejection

Claim Rejections - 35 USC § 112-Deposit Requirement

To the extent that claims 22, 24 and 26 depending on claims 1, 9 and 13, respectively, are required for the method of establishing and maintaining a healthy urogenital flora with *Lactobacillus iners* CCP-1, and to the extent that claims 21, 23 and 25, depending on claims 1, 9 and 13, respectively, are required for the method of establishing and maintaining a healthy urogenital flora with *Lactobacillus iners* Y16329, the following rejection applies.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly

connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New claims 21-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. **This is a new rejection necessitated by amendment of the claims in the response filed 10/02/2009.**

The specification lacks complete deposit information for the deposit of *Lactobacillus iners* Y16329 and *Lactobacillus iners* CCP-1. Because it is not clear that the properties of this strain are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the best mode disclosed by the specification requires the use of this specific strain, a suitable deposit for patent purposes is required.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of the deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of the deposit and the complete name and full street address of the depository is required.

If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR §1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

© the deposits will be maintained in a public depository for a period of at least thirty years from the date of the deposit or for the enforceable life of the patent or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become non-viable or non-replicable.

In addition, a deposit of the biological material that is capable of self-replication either directly or indirectly must be viable at the time of the deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of a biological material not made under the Budapest Treaty must be filed in the application and must contain:

- 1)The name and address of the depository;
- 2)The name and address of the depositor;
- 3)The date of deposit;
- 4)The identity of the deposit and the accession number given by the depository;
- 5)The date of the viability test;
- 6)The procedures used to obtain a sample if the test is not done by the depository; and
- 7)A statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the cell line described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR §1.801-1.809 for further information concerning deposit practice.

References made of record in a PTO-892 Form to complete the record

Dicks et al., Int J Syst Evol Microbiol. 2000 May;50 Pt 3:1253-8,

Conclusion

Claims 1, 2, 4, 5, 7, 9, 11, 13, 17, 18 and 21-26 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maria Leavitt/

Maria Leavitt

Primary Examiner, Art Unit 1633